

<b>STANFORD UNIVERSITY Research Consent Form</b>		<b><i>IRB USE ONLY</i></b>
<b>Protocol Director:</b> Wen-Kai Weng, MD, PhD	ep 16213	Approval Date: March 13, 2019 Expiration Date: March 13, 2020
<b>Protocol Title:</b> BMT 206: A Phase II Study of Non-myeloablative Allogeneic Transplantation Using Total Lymphoid Irradiation (TLI) and Antithymocyte Globulin (ATG) In Patients with Cutaneous T Cell Lymphoma		

STANFORD UNIVERSITY MEDICAL CENTER

Are you participating in any other research studies? \_\_\_\_\_ yes \_\_\_\_\_no

**INTRODUCTION TO RESEARCH STUDIES**

A research study is designed to answer specific questions, sometimes about a drug, device or treatment’s safety and its effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your personal doctor have a great deal of freedom in making decisions about your health care. When you are a research subject, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

**PURPOSE OF RESEARCH**

You are being invited to participate in a research study testing a new approach to allogeneic transplantation (transplant from another individual). This approach is called a non-myeloablative allogeneic transplant. In a non-myeloablative allogeneic transplant, the conditioning regimen (combination of radiation and an immune suppressing drug) given to prepare you to receive the donor’s hematopoietic (blood) cells weakens your immune system but does not completely eliminate your immune system.

In this study, the conditioning regimen is used to suppress your immune system sufficiently to allow your donor’s hematopoietic cells to grow and function. The possible effectiveness of this therapy relies on the use of the healthy donor’s blood and immune system destroying your cancer.

You were selected as a possible participant because you have a T cell lymphoma that involves the skin. Furthermore, you were selected because you have either a related or an unrelated donor available.

Your participation in this study is entirely voluntary.

Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice to you or effect on your medical care. If you decide to terminate your participation in this study, you should notify Dr. Wen-Kai Weng at [REDACTED]. Approximately 40 participants will be enrolled in this study.

**DURATION OF STUDY INVOLVEMENT**

This research study is expected to take approximately six to twelve months of active participation and life long follow up regarding your health status. Active participation may continue beyond twelve months if you are still experiencing transplant related problems, such as graft versus host disease.

**PROCEDURES**

MRN:
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If you choose to participate, the study plan is as follows:

- ◆ The first step is the placement of a central venous catheter.
- ◆ If you have extensive skin involvement with lymphoma, you will receive total skin electron beam therapy (TSEBT) for approximately 4 weeks prior to your transplant.
- ◆ You will then receive the conditioning regimen, combination of total lymphoid irradiation (TLI) and antithymocyte globulin (ATG) to weaken your immune system sufficiently allowing the donor's hematopoietic cells to grow and function.
- ◆ Infusion of the donor's hematopoietic cells. These cells are often called stem cells.
- ◆ Your immune system will be replaced by the donor's immune system. The success of a non-myeloablative allogeneic transplantation depends on the donor's immune system recognizing and destroying any cancer cells in your body.
- ◆ Administration of tacrolimus and mycophenolate mofetil (immune suppressing medications) to prevent graft versus host disease. Graft versus host disease is a reaction of the donor's immune system against your body tissues.
- ◆ If a month after transplant, you still have evidence of circulating tumor cells, called Sezary cells, then you will begin extracorporeal photopheresis (ECP) for a total of 12 treatments.

The following table shows the typical schedule:

Week One

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Admit to Hospital	Inpatient	Inpatient	Inpatient	Inpatient	Inpatient	Possible Discharge
	TLI ATG	TLI ATG	TLI ATG	TLI ATG	TLI ATG	

Week Two

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Outpatient	Outpatient	Outpatient	Outpatient	Outpatient	Outpatient	Outpatient
	TLI	TLI	TLI	TLI		
		Begin Tacrolimus			Transplant Begin Mycophenolate Mofetil	

Generally, you will receive total lymphoid irradiation (TLI) over a nine day period. Total lymphoid irradiation involves shielding or protecting your lungs, intestines and spinal cord with lead so that just

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your lymphoid organs (lymph nodes and spleen) receive radiation. The antithymocyte globulin (ATG) will be given once a day for five days. Following the TLI and ATG, the donor's hematopoietic cells will be infused. To prevent a reaction of the donor's immune system against your body tissues (a problem called graft versus host disease) you will receive two medications. These two medications, tacrolimus and mycophenolate mofetil, work by weakening the new donor immune system.

Blood tests will be performed frequently to evaluate your response to treatment and possible side effects of treatment. The amount of blood drawn will range from 3 to 6 tablespoons. Bone marrow tests will be done approximately at three months, six months and then annually. It is planned to give most of the treatment in the Infusion Treatment Area on the second floor of the Cancer Center. This will require that you temporarily relocate to be close to Stanford for approximately three months. You may require admission to the hospital for management of transplant complications.

In an effort to better understand both cancer and treatment outcomes, we will obtain tissue blocks from a previous biopsy of your tumor for analysis and the development of tissue arrays. A tissue array allows us to evaluate the types of proteins found on the tumor cells and assess the impact these various proteins have on outcomes. We will request these tissue blocks from your local oncologist and they will be returned to your local oncologist. No new biopsies will be needed; the material for the tissue arrays will be obtained from a previous biopsy.

### PHOTOGRAPHS

Photos of your skin will be taken to follow and document your skin response. Photos will be taken during your visit for skin evaluation at Cutaneous Lymphoma Clinic. Photos of your face will not be taken, in an effort to keep your identity undisclosed.

Do you agree to be photographed?  Yes  No

### WOMEN OF CHILDBEARING POTENTIAL

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

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To confirm to the extent medically possible that you are not pregnant, you agree to have a pregnancy test done before beginning this research study. You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

**REPRODUCTIVE RISKS FOR MEN**

The drugs used in this study may affect a fetus. Therefore you should not father a child while on this study and for 12 months after transplantation. Please ask for information about how to prevent pregnancy if you are having sex and are able to father a child.

**TISSUE SAMPLING FOR GENETIC TESTING, OTHER TESTING, OR BANKING FOR FUTURE RESEARCH**

Research using tissues is an important way to try to understand human disease and/or the role genes play in disease. You have been given this consent form because the investigators want to include your tissues in a research project, or because they want to save such samples for research.

There are several things you should know before allowing your tissues to be studied:

Your tissues will be stored using a unique identifier. This unique identifier is linked to your name. The database linking your name and the unique identifier is maintained securely and access is limited to those individuals in the Blood and Marrow Transplant Program. Your name or other public identifiers will not be included with any data shared with other investigators outside of Stanford.

Disease testing and genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease. Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. Donation of tissues for these research purposes is not genetic testing.

Even with special precautions, there is no absolute protection against discrimination on the basis of disease or genetic information. For this reason, the investigator will use the results of this study as

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research only and not include them in your medical record. Generally, you will not be told the results, even if there might be some potential benefit to you.

You have the right to refuse to allow your tissues to be studied now or saved for future study. You may withdraw from this study at any time. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not for additional research.

Investigators in this study may try to contact you in the future. If you are contacted and want to know what the investigators have learned about your tissue samples, you should understand the following possibilities: Information may be too sketchy to give you particular details or consequences.

Any tissues you have donated which are used in research may result in new products, tests, or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests, or discoveries.

I consent to my samples being saved for future research

I do not consent to my samples being saved for future research

## **SUBJECT'S RESPONSIBILITIES**

You should:

- Follow the instructions of the Protocol Director and study staff.
- Take all prescribed medications as directed.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from all of the Protocol Directors. This is to protect you from possible injury arising

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from such things as extra blood drawing, extra x-rays, the possible interaction(s) of research drugs, or other similar hazards.

## **WITHDRAWAL FROM STUDY**

If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw from the study at any time you should notify Dr. Wen-Kai Weng by phoning (650)723-0822. The consequences of withdrawing from the study would be entirely dependent on when during the study treatment you withdraw. You should discuss your decision to withdraw with the protocol director, Dr. Wen-Kai Weng, so the consequences of your decision can be explained to you.

The Protocol Director may also withdraw you from the study and the study medication may be stopped without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and/or study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy.
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

## **POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES**

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director, Dr. Wen Kai Weng, if you have any questions.

### **Central Venous Catheter**

A central venous catheter (a catheter much like an intravenous catheter but larger and placed on the chest) will be placed in the large vein under your collarbone. This will be done under local anesthesia. The catheter can be used for administering fluids, medications, nutritional support, blood products and to obtain blood samples so you are not subjected to repeated needle sticks. Potential problems with the catheter include pain and bleeding at the insertion site, infection, poor functioning, clotting and

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rarely a pneumothorax (puncture of the lung). In some cases, these problems lead to the need to remove the catheter. Generally, the catheter remains in place until you are eating and drinking adequately, able to maintain a good nutritional state and no longer requiring transfusions.

**Total Skin Electron Beam Therapy (TSEBT)**

Total skin electron beam therapy is a type of radiation administered to the skin to treat lymphoma that involves the skin. If you have extensive skin involvement with lymphoma, approximately 4 weeks prior to your transplant you will receive electron beam radiation to your skin. You will receive the radiation to your skin 4 times per week. The most common side effect is skin damage, which looks and feels like a severe sun burn. A severe skin reaction is most likely in individuals who tend to burn easily in the sun. The skin reactions are treated with supportive agents until the skin heals. Long term effects from TSEBT include dry skin, loss of sweat and oil secretion, dilated blood vessels, changes in skin coloring, partial or complete hair loss in men and hair thinning in women.

**Total Lymphoid Irradiation (TLI)**

TLI will be administered to weaken your immune system to enable your donor's cells to grow. The side effects of radiation include nausea and diarrhea. Radiation will lower the blood counts with the associated risks of infection, bleeding and anemia. Radiation can cause sterility and there is a risk of genetic damage to children produced soon after transplantation. Radiation has also been associated with second malignancies and hypothyroidism. There is increased risk to viral infections within two years following this type of radiation.

**Antithymocyte Globulin (ATG)**

ATG is given to weaken your immune system so the donor's cells will grow. The ATG will be given intravenously over 5 days. Side effects of ATG include fever, chills, rash, allergic reactions, muscle and joint aches, and a decrease in platelet counts. Serious life-threatening allergic reactions, although rare, can be seen with this medication. ATG weakens the immune system leaving you more susceptible to infections and therefore you will be monitored frequently for evidence of infection.

**Allogeneic Hematopoietic Cell Transplant**

The infusion of the donor's cells is similar to a blood transfusion. In most cases the infusion of the donor's cells occurs without side effects. In rare instances, a severe life-threatening allergic reaction called anaphylaxis can occur. Two to four weeks after the infusion of the donor's cells, your blood counts will begin to recover. Your donor may be a sibling (brother or sister) or an unrelated volunteer donor.

**Graft-versus-Host Disease**

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After the graft (donor’s hematopoietic cells) begins to function, there is a risk of a reaction of the donor’s cells against your tissues. This reaction is called graft versus host disease. Acute graft versus host disease develops within the first three months following transplant. The most common organs affected by acute graft versus host disease are: 1) the skin with a rash, peeling, and/or deeper tissue injury, 2) the stomach and intestines with diarrhea, cramping and bleeding, and 3) the liver with inflammation and/or failure. Chronic graft versus host disease may occur anytime in the first year after transplantation and may involve problems with the eyes, mouth, skin, throat, lungs, lining of the heart and lungs, vagina, muscles, nerves and liver. Both acute and chronic graft versus host disease may become severe enough to result in death. Graft versus host disease can also negatively impact your quality of life. The risk of graft versus host disease is higher if you have an unrelated volunteer donor. You will be receiving tacrolimus and mycophenolate mofetil to prevent graft versus host disease. If you develop graft versus host disease you will be given additional drugs. All of these medication work by weakening the new (donor) immune system, leaving you more susceptible to infections.

**Tacrolimus**

This medication is used to try to prevent graft versus host disease. Common side effects include nausea, vomiting, high blood pressure, shaking of the hands, increased hair growth, kidney damage, liver damage and diabetes. Less common side effects include changes in mental function, a process of destruction of red blood cells, and seizures. These side effects generally go away when the dose of the medication is decreased. Tacrolimus works by weakening the immune system therefore as long as you are taking tacrolimus you are more susceptible to infections. Infections can sometimes be life-threatening. Immune suppressing medications are also associated with the development of secondary malignancies.

Tacrolimus can be taken as a pill or intravenously (through your catheter). The tacrolimus will begin three days prior to receiving your donor’s hematopoietic cells and you will need to take the tacrolimus for at least 6 months. You may need to take it longer if you develop graft-versus-host disease.

**Mycophenolate Mofetil**

Side effects of mycophenolate mofetil include a decrease in the blood counts, which is usually reversible when the drug is stopped. Other side effects include nausea, vomiting, diarrhea, abdominal discomfort and bleeding. Mycophenolate mofetil works by weakening the immune system therefore as long as you are taking mycophenolate mofetil you are more susceptible to infections. Infections can sometimes be life-threatening. Immune suppressing medications are also associated with the development of secondary malignancies.

Mycophenolate mofetil will be given as a pill two to three times per day. It will begin on the day you receive you donor’s hematopoietic cells. If your donor is a sibling, the mycophenolate mofetil will

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continue for approximately one month. If your donor is an unrelated volunteer, the mycophenolate mofetil will continue for approximately 3 months.

**Low Blood Counts**

The TLI and ATG will lower your blood counts. When your white blood cell count is low, you are at risk for infections. You will be asked to follow many guidelines to protect yourself from infections, including wearing a special mask, hand washing, special diet, special mouth care treatments, taking medications to prevent infections, and avoiding ill people. Infections can be caused by a virus, bacteria or fungus and in some cases be life-threatening. When your platelet count is low there is a risk of bleeding. Rarely, bleeding can be life-threatening. You will receive transfusions of platelets to minimize the risk of bleeding. Your red blood cell count will be low leaving you anemic and feeling tired. You will receive transfusions of red blood cells to treat the anemia. In some individuals the need for transfusions can last for many months following transplant.

**Extracorporeal Photopheresis (ECP)**

Approximately one month after transplant, if you still have circulating tumor cells, called Sezary cells, then you will begin ECP therapy. Extracorporeal photopheresis is a procedure that will expose your blood to radiation to try and kill lymphoma cells that are circulating in the blood. You will receive a weekly treatment for one month, then every other week for four treatments, then monthly for four treatments, for a total of 12 treatments over seven months.

ECP is an approved procedure for the treatment of cutaneous T cell lymphoma. To perform ECP, either using your central venous catheter or intravenous needled inserted into you arm, blood (including T cells) is removed from your body and circulates through an apheresis machine. While your blood is in the machine it is mixed with 8-methoxypsoralen. The blood is then exposed to ultraviolet radiation which kills the T cells. After the blood is exposed to the ultraviolet radiation, it is returned back to you. The ECP takes approximately 3 hours.

ECP is generally very well tolerated. During the ECP your may experience a low blood pressure or slight fever. Other side effects can include skin itching or redness. If you have elevated levels of lipids (or fats) in your blood, the ECP may be less effective.

**Graft Rejection**

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There is a risk that the donor's hematopoietic cells will not start growing following infusion. If the donor's cells fail to grow, it is anticipated that your own blood counts would recover. However, if the donor's cells do not grow and your blood cells do not recover, this is a fatal complication.

**Unexpected Organ Damage and Other Side Effects**

It is possible you may experience unexpected, life-threatening heart, lung, kidneys, brain, or liver damage as a result of the transplant. The long-term effects upon heart, lung, kidneys, brain and liver are unknown. There may be as yet unknown side effects and risks associated with non-myeloablative allogeneic transplantation.

**Infertility and Sexual Functioning**

It is possible that this therapy will leave you unable to have children in the future. It is advised that you continue to use birth control however to avoid an unplanned pregnancy. If you are a woman, this therapy may also induce menopause. In most cases sexual functioning is not affected, although both men and women often report less interest in sexual activity for many months following treatment. In some cases men report difficulty with erections and women report pain with sexual intercourse.

**Secondary Malignancies**

There is also a risk you may develop a second cancer as a result of the radiation, antithymocyte globulin and immunosuppressive therapy.

**Relapse**

Despite receiving a non-myeloablative allogeneic transplant, there remains a risk that your cancer could return following transplant.

**Bone Marrow Biopsies and Venipuncture**

Bone marrow biopsies and venipuncture (drawing) blood can be painful. There is a risk of bruising or bleeding and a very small risk of infection at the puncture site.

**POTENTIAL BENEFITS**

It is possible that the allogeneic transplant may cure your malignancy. A possible benefit of this therapy to you and to others is the discovery of a means of reducing the risk of graft versus host disease and improving the safety of allogeneic transplantation.

**WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.**

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**ALTERNATIVES**

Alternative procedures that might be advantageous include a standard allogeneic transplant, continuing standard therapies, other investigational therapies or no therapy. You should discuss each of these alternatives with your physician.

**SUBJECT’S RIGHTS**

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

If you decide not to participate, tell Dr. Wen-Kai Weng. You will still receive care for your disease and will not lose any benefits to which you would otherwise be entitled.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study. You have the right to review your medical records. Results from diagnostic testing, laboratory findings and the results from examinations will be discussed with you.

**ClinicalTrials.gov**

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**CONFIDENTIALITY**

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

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## FINANCIAL CONSIDERATIONS

### PAYMENT

You will not be paid to participate in this research study.

### COSTS

If you participate in this study, there may be additional costs to you. These include the personal time it will take to come to all of the study visits. The study will pay for those services, supplies, procedures, and care associated with this study that are not a part of your routine medical care. If you would like to review the list of such covered services, supplies, procedures and care, please tell us now or at any time during the study.

Participation in this study is not a substitute for health insurance. You and/or your health insurance must pay for those services, supplies, procedures, and care that you require during this study for routine medical care. You will be responsible for any co-payments and/or deductibles as required by your insurance.

The Institute of Immunity, Transplantation and Infection is providing financial support and/or material for this study.

## **Authorization to Use Your Health Information for Research Purposes**

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the consent form and as required or allowed by law. Please read it carefully before signing it.

### **What is the purpose of this research study and how will my health information be utilized in the study?**

The purpose of this research is to continue to explore, understand and improve outcomes in the field of blood and marrow transplantation. Information about you and your treatment will be used to understand and improve outcomes in blood and marrow transplantation.

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**Do I have to sign this authorization form?**

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

**If I sign, can I revoke it or withdraw from the research later?**

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must contact: Dr. Wen-Kai Weng at Stanford University Medical Center, Stanford, CA 94305 or phone [REDACTED]

**What Personal Information Will Be Used or Disclosed?**

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to your age, gender, ethnic background, disease and treatment related information.

**Who May Use or Disclose the Information?**

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, Dr. Wen-Kai Weng
- The research team which includes your physician, laboratory research staff, nursing staff and study coordinators who gather and document your data.
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary.

**Who May Receive / Use the Information?**

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The Food and Drug Administration

MRN:
NAME:



STUDY

<b>STANFORD UNIVERSITY Research Consent Form</b>		<b><i>IRB USE ONLY</i></b>
<b>Protocol Director:</b> Wen-Kai Weng, MD, PhD	ep 16213	Approval Date: March 13, 2019 Expiration Date: March 13, 2020
<b>Protocol Title:</b> BMT 206: A Phase II Study of Non-myeloablative Allogeneic Transplantation Using Total Lymphoid Irradiation (TLI) and Antithymocyte Globulin (ATG) In Patients with Cutaneous T Cell Lymphoma		

- Federal and regulatory agencies as required
- Data Safety Monitoring Board
- Center for International Blood and Marrow Transplant Research (CIBMTR)
- The National Marrow Donor Program or donor registry from which the donors cells were obtained
- Foundation for the Accreditation of Cellular Therapy
- The National Institutes of Health

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

**Will access to my medical record be limited during the study?**

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g. if included in your official medical record).

**When will my authorization expire?**

Your authorization for the use and/or disclosure of your health information will expire on May 1, 2100.

\_\_\_\_\_  
Signature of Adult Participant \_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of Adult Participant \_\_\_\_\_  
Date

**CONTACT INFORMATION**

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Wen Kai Weng at [REDACTED]. You should also contact him at any time if you feel you have been hurt by being a part of this study.

If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team

MRN:
NAME:



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at [REDACTED] or toll free at [REDACTED] You can also write to the Stanford IRB, Stanford University.

If you need to change your appointment, please contact Dr. Wen-Kai Weng at [REDACTED]

**COMPENSATION**

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

Additionally, Stanford is not responsible for research and medical care by other institutions or personnel participating in this study. You do not waive any liability rights for personal injury by signing this form.

**EXPERIMENTAL SUBJECT’S BILL OF RIGHTS**

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;

MRN:
NAME:



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- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

\_\_\_\_\_  
Signature of Adult Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of Adult Participant

\_\_\_\_\_  
Date

The following witness line is to be signed only if the consent is provided in summary form and accompanied by a short form foreign language consent.

MRN:
NAME:



STUDY

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\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of Witness

\_\_\_\_\_  
Date

(e.g., staff, translator/interpreter, family member, or other person who speaks both English and the participant's language)

- Translated short form must be signed and dated by both the participant (or their LAR) and the witness.
- The English consent form (summary form) must be signed by the witness and the POC.  
The non-English speaking participant does not sign the English consent.
- The non-English speaking participant should not sign the HIPAA participant line

**Person Obtaining Consent**

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of Person Obtaining Consent

\_\_\_\_\_  
Date

MRN:

NAME:



STUDY